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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,009	07/29/2003	Henrik Ditzel	1361.005US2	8535

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EXAMINER	
CHAUDHURI, ANIRUDDHO RAY	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,009	DITZEL ET AL.	
	Examiner	Art Unit	
	Aniruddho R Chaudhuri	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11,24,28,30,33,38,39,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-11,24,28,30,33,38,39,44 and 45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendments

1. Applicant's amendment, filed 07/29/03, is acknowledged.
Claims 1, 12-23, 25-27, 29, 31, 32, 34-37, 40-43 and 46 have been canceled.
Claims 3, 7, 11, 33 and 39 have been amended.
Claims 2-11, 24, 28, 30, 33, 38, 39, 44 and 45 are pending.

Sequence Compliance

2. The instant application is in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. Claims 2-10 and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

It is noted that the preamble of claim 2 is drawn to an antibody while the dependent claims 3-10, 33 are drawn to immunopolypeptide.

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g. see page 33-35 of the specification. Applicant is required to review the instant specification for similar errors and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Restriction

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-11, 33, drawn to an anti-human-glucose-6-phosphate isomerase antibody (e.g. immunopolypeptide) and pharmaceutical compositions classified in Class 530, subclass 387.1, and Class 424, subclass 130.1.

II. Claim 24, drawn to an antisense oligonucleotide molecule, classified in Class 536, subclass 24.5.

III. Claim 28, drawn to a composition comprising glucose-6-phosphate isomerase, classified in Class 514, subclass 2.

IV. Claim 30, drawn to a nucleotide sequence encoding immunopolypeptide, classified in Class 536, subclass 23.5.

V. Claim 38, drawn to a method of diagnosing of autoimmune disease to the extent it reads on using an antibody (e.g. immunopolypeptide), classified in Class 435, subclass 7.1.

It appears that the only agent employed in the method of diagnosing disclosed in the specification as filed is an antibody (e.g. see page 35 of the specification). If applicant intends to claim other methods of diagnosing with non-antibody agents, then such methods would be subject to further restriction.

VI. Claim 39, drawn to a method of treating an autoimmune disease with an immunopolypeptide (e.g. antibody), classified in Class 424, subclass 130.1.

VII. Claims 44, drawn to a method of treating disease by filtering the patient's blood through a filter containing human-glucose-6-phosphate isomerase, classified in Class 514, subclass 8.

VIII. Claims 45, drawn to a method of treating an autoimmune disease by administering human-glucose-6-phosphate isomerase, classified in Class 514, subclass 885.

6. Groups I, II, III and IV are different products. Antibodies, antisense oligonucleotides, proteins and nucleotides differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is distinct. Therefore, they are patentably distinct.

7. Groups V/VI/VII/VIII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints, which require non-coextensive searches; therefore, each method is patentably distinct.

8. (Groups I and V/VI), and (Groups III and VII/VIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the antibody of Group I can be used for affinity purification, in addition to the methods of treating and diagnosing recited.

In the instant case, the human-glucose-6-phosphate isomerase of Group III can be used as an immunogen to produce antibodies, in various in vitro assays, in addition to the methods of treating recited.

9. (Groups I and VII/VIII), (Groups II and V-VIII), (Groups III and V/VI), and (Groups IV and V-VIII) are not related as product and process of using.

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for an examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

11. This application contains claims directed to the following patentably distinct species of the claimed Groups I, V and VI wherein:

If Groups I, V, VI are elected: applicant is required to elect a particular anti-human-glucose-6-phosphate isomerase antibody, e.g. see claims 2-11;

Applicant is further required to provide the following information with respect to the elected species:

applicable CDR sequence from SEQ ID NO's: 15-56; e.g. see claims 3-4;
and
applicable spacer amino acid sequence from SEQ ID NO's: 57-108; e.g. see claims 5-6;

It is noted the claims recite CDR's and spacer amino acids e.g. see claims 3-6. Applicant should elect a particular CDR and a particular spacer amino acid sequence that read on a functional anti-human-glucose-6-phosphate isomerase antibody.

Otherwise, the election of CDR's and spacer amino acid sequences that do not result in a functional anti-human-glucose-6-phosphate isomerase antibody would be subject to a rejection under 35 USC 112, first paragraph, enablement.

The anti-human-glucose-6-phosphate isomerase antibodies are distinct because each antibody possesses a unique structure as determined both the CDR **and** the spacer amino acid sequence, and by the pairing of those sequences to produce the antigen-binding site.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

12. It is noted that the only autoimmune disease disclosed in the specification as filed appears to be arthritis. Therefore, no species election on autoimmune diseases with respect to Groups V-VIII is set forth herein.

Applicant is invited to limit the claims to recite arthritis.

Alternatively, if the specification does disclose autoimmune diseases other than arthritis, then such autoimmune diseases would be subject to a species election, given that autoimmune diseases differ in etiologies and therapeutic endpoints.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aniruddho Ray Chaudhuri whose telephone number is 571-272-0953. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 15, 2004

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